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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,324	09/29/2003	Mark B. Knudson	14283.1US13	4634
7590	03/24/2006		EXAMINER	
Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903			REIDEL, JESSICA L	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/674,324	KNUDSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jessica L. Reidel	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
  - 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/04, 01/04, 02/04, 04/04, 07/04, 08/04,</u><br><u>09/04, 01/05, 05/05, 08/05, 02/06</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group II, Claims 12-19 in the reply filed on March 9, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Priority*

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/358,093, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, there is no support or enablement provided in the disclosure of Application No. 10/350,093 for a method comprising applying an electrical blocking signal to a vagus nerve at a blocking site to at least partially block nerve impulses to an organ.

***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on January 2, 2004, January 23, 2004, February 9, 2004, April 12, 2004, July 19, 2004, August 9, 2004, September 28, 2004, January 21, 2005, May 26, 2005, August 31 2005 and February 2, 2006 have been acknowledged and are being considered by the Examiner.

***Specification***

4. The disclosure is objected to because of the following informalities: the "Cross-Reference to Related Applications" should be updated to include the serial numbers of the referenced Applications. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12-14 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Osorio et al. (U.S. 6,341,236) (herein Osorio). As to Claim 12, Osorio discloses a method for treating epilepsy with minimized or no effect on the heart (see Osorio Abstract) comprising electrically stimulating a vagus nerve 60 of a patient at a stimulation site with a stimulation signal selected to have a therapeutic effect on a target organ (i.e. the brain) while applying an electrically blocking signal (i.e. anodal currents or high frequency stimulation) to the vagus nerve 60 at a blocking site (anode of the electrode pair) on a side of the stimulation site opposite the target organ (i.e. the brain) where the blocking signal is selected to at least partially block

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nerve impulses to a second organ (i.e. the heart 55) on a side of the blocking site opposite the stimulation site (cathode of the electrode pair) (see Osorio Fig. 12A, column 6, lines 53-67 and column 7, lines 1-61).

7. As to Claim 13, Osorio further discloses that a signal generator 20 may be used to vary the pulsing parameters of the pulse signal applied to the vagus nerve 60 (see Osorio column 5, lines 13-34 and lines 47-54).

8. As to Claim 14, Osorio further discloses that physiological signals sensed via sensor 15 of the heart 55 may be used to regulate the pulse signal applied to the vagus nerve 60 (see Osorio column 3, lines 9-11 and lines 35-42 and column 4, lines 45-65).

9. As to Claim 17, Osorio further discloses that the target organ is a brain and the second organ is a heart 55 (see Osorio Figs. 12A-12B, Abstract, column 3, lines 23-63, column 6, lines 53-67, column 7, lines 1-61 and column 8, lines 7-10).

10. As to Claims 18-19, Osorio further discloses that the disorder is epilepsy, which is a disorder associated with the central nervous system (see Osorio Figs. 12A-12B, Abstract, column 1, lines 5-48, column 3, lines 23-63, column 6, lines 53-67, column 7, lines 1-61 and column 8, lines 7-10).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio in view of Cohen et al. (U.S. 6,684,105) (herein Cohen). Osorio discloses the claimed invention as discussed above except that the target organ is not a gastro-intestinal organ and the method is no any one of a plurality of gastrointestinal diseases.

Cohen, however, discloses a method for treating many conditions of a subject using an electrode device that is adapted to be coupled to longitudinal nervous tissue of the subject (i.e. the vagus nerve) and a control unit that is adapted to drive the electrode device to apply to the nervous tissue a current which is capable of inducing action potentials that propagate in the nervous tissue in a first direction, so as to treat the desired condition. Cohen further discloses that the control unit is further adapted to suppress action potentials from propagating in the nervous tissue in a second direction opposite to the first direction to avoid inducing possible unwanted side effects both proven and potential of selective stimulation of the vagus nerve (see Cohen Abstract, column 1, lines 6-31 and column 2, lines 31-33). Cohen further discloses that this method and apparatus may be used to stimulate a portion of the vagus nerve innervating the stomach in order to stimulate sensory fibers and thereby produce a sensation, e.g., satiety or hunger while avoiding inadvertently reducing or otherwise affecting the heartbeat of the patient (see Cohen column 5, lines 20-39). Cohen also teaches that the method and apparatus may be used to treat any disorder of an organ or organ system of a patient that is modulated by the vagus nerve (see Cohen column 1, lines 6-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Osorio in view of Cohen to include an embodiment where the target organ is one of the gastro-intestinal tract (such as the stomach) to allow for treatment of any one of a plurality of gastrointestinal

disorders (which are modulated by vagal nerve activity) without inadvertently affecting the beating of the heart of a patient to better the invention.

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 9, 17-20 and 23 of copending Application No. 10/756,166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, 10, 19-21 and 24-31 of copending Application No. 10/756,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5 and 8-14 of copending Application No. 10/675,818. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Conclusion*

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fang et al. (U.S. 5,199,430) discloses a method where action potentials are electrically excited to propagate downstream on smaller diameter nerve fibers causing contraction of the bladder and concurrently, blocking action potentials are allowed to propagate upstream on larger diameter nerve fibers, collision blocking naturally occurring.

King (U.S. 6,928,320) also discloses a method and an apparatus for blocking activation of tissue or conduction of action potentials while other tissue is being therapeutically activated.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Jessica L. Reidel*  
Jessica L. Reidel 03/19/06  
Examiner  
Art Unit 3766

*Robert E. Pezzuto*  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766